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- b) precipitating the adduct by cooling, and  
c) separating the adduct from the water and organic solvent.

38. (New) The adduct of mirtazapine and water of claim 37 wherein the organic solvent is an alcohol.

39. (New) The adduct of mirtazapine and water of claim 38 wherein the alcohol is selected from the group consisting of methanol, ethanol and isopropyl alcohol.

40. (New) The adduct of mirtazapine and water of claim 39 wherein the alcohol is ethanol.

41. (New) The adduct of mirtazapine and water of claim 40 wherein from about one to about four volumes of water are added relative to the amount of ethanol.

42. (New) The adduct of mirtazapine and water of claim 37 containing up to about three weight percent water.

43. (New) The adduct of mirtazapine and water of claim 37 wherein the elevated temperature is about the reflux temperature of the organic solvent.

44. (New) A pharmaceutical composition comprising a therapeutically effective amount of the adduct of mirtazapine and water of claim 29 and a pharmaceutically acceptable carrier.

45. (New) A method of treating depression by administering to a human patient in need of such treatment a pharmaceutical composition of claim 44.

#### REMARKS

Applicants have elected to pursue subject matter that has been classified in Group IV (office action mailed Jan. 5, 2001). The Applicants agree that claim 25 of Group IV is drawn to a different invention from the other Groups (and from claims 26-28

of Group IV) and do not traverse the restriction as to Group IV: Applicants desire not to forfeit at this time the right to traverse the restriction of Groups I, II and III from each other in the prosecution of one or more divisional applications. Applicants have cancelled the original claims of Group IV and desire to pursue subject matter classified by the Examiner in Group IV with new claims 29- 45. Thus, claims 29-45 are now pending in this application.

Claims 29-43 are directed to an adduct of mirtazapine and water. Applicants submit that claims 29-43 more particularly point out and distinctly claim applicant's invention that did original claim 25. New claims 44 and 45 claim a pharmaceutical composition containing the adduct and a method of treating depression by administering the pharmaceutical composition to a patient. Claims 44 and 45 parallel original claims 27 and 28. However, the base claim is to the adduct rather than to a novel process of Applicant's invention for preparing the compound mirtazapine.

The new claims are fully supported by Applicants' specification. Claims 29-43 are directed to an "adduct of mirtazapine and water." Support may be found in the specification on page 10, lines 18-21, and in originally-filed claims 24 and 25.

Claim 30 allows that the adduct may contain up to about three weight percent water. Support for claim 30 may be found on page 10, lines 21, 22.

Claim 31 is a product-by-process claim to the novel adduct which may be made by precipitation from a solvent comprising water and either an alcohol or acetone. Support for claim 31 may be found on page 10 and in Example 6 of the specification. In particular, at p. 10, line 4, it is stated that "solvent systems such as alcohol-water can be used in the recrystallization of crude mirtazapine" as claimed in claim 32. The preferred alcohols listed in claim 33 are identified at p. 10, line 6 and are used in Example 6 (Table

1). The use of the most preferred alcohol, ethanol, as claimed in claim 34, is described in the first and third full paragraphs on page 10, along with the most preferred ethanol water mixtures of claim 35. Claim 36 parallels claim 30 and is supported in the same manner as that claim.

Claim 37 is a product-by-process claim to the novel adduct of mirtazapine and water prepared by an especially preferred process, which is described in the second and third full paragraphs on page 10 and is exemplified in Example 6. Claims 38-42 parallel claims 32-36 and are support in the same manner as those claims. In claim 43, the elevated temperature is at about the reflux temperature of the organic solvent used in the process by which the adduct is obtained in claim 37. This limitation is supported at p. 10, lines 12-14 and 18, 29.

### CONCLUSION

In view of the foregoing, Applicants respectfully submit that claims 29-45 are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. The Patent Office is authorized to charge any fees which may be necessary for consideration of this paper to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,  
KENYON & KENYON

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